

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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FEB 28 2000

GRAYCARY/GT PATENT
WRITTEN OPINION

(PCT Rule 66)

To: STEPHEN E. REITER
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Date of Mailing
(day/month/year)

16 FEB 2000

Applicant's or agent's file reference

INVIT1100WO

REPLY DUE

within ONE months
from the above date of mailing

International application No.

PCT/US99/02442

International filing date (day/month/year)

04 FEBRUARY 1999

Priority date (day/month/year)

04 FEBRUARY 1998

International Patent Classification (IPC) or both national classification and IPC
IPC(7): G01N 33/53, 33/48; 33/543 and US Cl.: 435/7.1, 6; 436/518, 536, 501, 543

Applicant

INVITROGEN

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 *bis*.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 04 JUNE 2000

Name and mailing address of the IPEA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

T. WESSENDORF

Telephone No. (703) 308-0196

I. Basis of the opinion

1. This opinion has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".)*:

- ☒ the international application as originally filed.
- ☒ the description, pages 1-47 , as originally filed.
 pages NONE , filed with the demand.
 pages NONE , filed with the letter of _____
- ☒ the claims, Nos. 1-50 , as originally filed.
 Nos. NONE , as amended under Article 19.
 Nos. NONE , filed with the demand.
 Nos. NONE , filed with the letter of _____
- ☒ the drawings, sheets/fig 1-7 , as originally filed.
 sheets/fig NONE , filed with the demand.
 sheets/fig NONE , filed with the letter of _____

2. The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

3. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:
 NONE

WRITTEN OPINION

International application No.

PCT/US99/02442

IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees the applicant has:

- ☐ restricted the claims. (See Supplemental Sheet)
- ☒ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1 not to invite the applicant to restrict or pay additional fees:

3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this opinion:

- ☒ all parts.
- ☐ the parts relating to claims Nos. .

WRITTEN OPINION

International application No.

PCT/US99/02442

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

Novelty (N)	Claims <u>31-40</u>	YES
	Claims <u>1-30, 41-50</u>	NO
Inventive Step (IS)	Claims <u>none</u>	YES
	Claims <u>1-50</u>	NO
Industrial Applicability (IA)	Claims <u>1-50</u>	YES
	Claims <u>none</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-2 lack novelty under PCT Article 33(2) as being anticipated by Ekins.

Ekins discloses at e.g., page 337, Summary; page 346, col. 2 up to page 352, col. 1, a method of identifying antibodies having binding affinity for an analyte (e.g., antigen) comprising contacting a microspot array of antibodies on a solid surface with an antigen and identifying said antibodies which fully meets the broad claimed method.

Claims 1-4, 6, 9-10, 17, 28-29 lack an inventive step under PCT Article 33(3) as being obvious over Chang. Chang however, discloses at e.g., col. 3, line 55 up to col. 8, line 15, a method by which a large number of different antibody-coated spots in the form of array are assembled on a surface of a support and then contacted with a wide range of antigens. Chang however does not expressly disclose that said method is to identify for the antibodies that bind to the antigen. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to identify the antibodies using known immunoassay method since Chang discloses identifying the antigen that binds to the antibodies instead of vice versa, as recited. Note the suggested teachings of Chang at col. 4, lines 64-66 as to the use of determining the isotypes, allotypes of an antibody and the typing of a viral or a bacterial sample. It would have been within the ordinary skill of one in the art to identify either the antibody or antigen of an antigen-antibody complex.

Claims 41-50 lack novelty under PCT Article 33(2) as being anticipated by Ramsay.

The method steps disclosed by Ramsay at e.g., paragraph bridging col. 1 and col. 2 of page 41 up to page 44 fully meets the recited method.

Claims 1-30, 41-50 lack novelty under PCT Article 33(2) as being anticipated by Hollis et al.

The claimed invention drawn to the different methods of (Continued on Supplemental Sheet.)

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

IV. LACK OF UNITY OF INVENTION:

1. This response is made to a telephone Lack of Unity requirement (see telephone memorandum attached hereto or attached to a prior Written Opinion).

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

identifying antibodies using an array of uncharacterized antibodies on a solid surface, a method of diagnosing a disease and a method of comparing protein expression patterns are fully met by the process steps of Hollis at e.g., col. 4, line 21 up to col. 18, line 63.

Claims 31-40 lack an inventive step under PCT Article 33(3) as being obvious over Hollis in view of CAMBRIDGE ANTIBODY TECHNOLOGY LIMITED.

Hollis is discussed, above. Hollis fails to disclose a kit. However, CAMBRIDGE ANTIBODY TECHNOLOGY LIMITED discloses a kit. It would have been obvious to make a kit comprising an array of uncharacterized antibodies for its commercial expediency and for the positive teachings of CAMBRIDGE ANTIBODY TECHNOLOGY LIMITED of making a kit.

Claims 1-50 meet the criteria set out in PCT Article 33(4), because the claimed invention has industrial applicability in e.g., diagnosis.

NEW CITATIONS

US 5,653,939 A (HOLLIS et al) 05 August 1997, entire document.

WO 93/19172 A1 (CAMBRIDGE ANTIBODY TECHNOLOGY LIMITED) 30 SEPTEMBER 1993, entire document.